# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| AVENTIS PHARMA S.A.,<br>SANOFI-AVENTIS U.S., LLC |                              |
|--|------------------------------|
| Plaintiffs,                                      | C.A. No. 1:07-cv-00721 (GMS) |
| v.   |                              |
| HOSPIRA, INC.                                    |                              |
| Defendant.                                       |                              |

# **JOINT STATUS REPORT**

Pursuant to Rule 16, Fed. R. Civ. P., D. Del. LR 16.2, and the Court's Notice of Scheduling Conference, the parties, by and through their undersigned counsel, jointly submit this Status Report. Counsel for the parties participated in a telephone conference pursuant to the Notice of Scheduling Conference and as required by Fed. R. Civ. P. 26(f) on April 1, 2008. Michael J. McCabe II of Finnegan, Henderson, Farabow, Garrett, and Dunner LLP and Steven J. Balick of Ashby & Geddes participated via telephone on behalf of the plaintiffs, and Kathleen Barry of Winston & Strawn LLP participated via telephone on behalf of the defendant.

## 1. Jurisdiction and Service:

The parties agree that the Court has subject-matter jurisdiction over Plaintiffs' claims and Defendant's counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a). The parties further agree that the Court has personal jurisdiction over each of the parties. No parties remain to be served.

## 2. Substance of the Action:

Plaintiffs state that they sell drug products containing docetaxel in the United States under the brand name Taxotere<sup>®</sup>, pursuant to NDA 020-449 held by Sanofi-Aventis US LLC. Plaintiffs allege that use of these drug products is covered by United States Patent Nos. 5,714,512 ("the '512 patent") and 5,750,561 B1 ("the '561 patent"). Plaintiffs allege that Defendant's submission of NDA 22-234 constitutes infringement of one or more of the claims of the '512 and '561 patents. Plaintiffs further allege that they will be substantially and irreparably harmed by Defendant's infringement.

Defendant states that it filed NDA 22-234 with the FDA seeking approval for a docetaxel injection product. Defendant's NDA includes paragraph IV certifications to the '512 and '561 patents. Defendant sent Plaintiffs a statutorily-required notice letter of its paragraph IV certifications on September 28, 2007. Defendant contends that no valid claim of the '512 and '561 patents will be infringed by the manufacture, use or sale of its proposed NDA product. Defendant further contends that the '512 and '561 patents are invalid and unenforceable.

## 3. Identification of Issues:

The factual and legal issues genuinely in dispute are: (1) whether the manufacture, use and/or sale of Defendant's proposed NDA product would infringe the '512 and '561 patents, (2) whether the '512 and '561 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, and (3) whether the '512 and '561 patents are unenforceable.

## 4. Narrowing of Issues:

No motions are currently before the Court. The parties expect that, as discovery proceeds and the case progresses, they may be able to narrow the issues by way of stipulation or dispositive motions.

## 5. Relief:

Plaintiffs seek a judgment: (1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hospira's submission to the FDA of NDA No. 22-234 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hospira's docetaxel injection product before the expiration of the '512 and '561 patents was an act of infringement of the '512 and '561 patents; (2) declaring that Hospira's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hospira's docetaxel injection product would constitute infringement of the '512 patent and '561 patents; (3) ordering that the effective date of any FDA approval of Hospira's docetaxel injection product shall be no earlier than the expiration of the '512 patent and '561 patents, in accordance with 35 U.S.C. § 271(e)(4)(A); (4) enjoining Hospira and all persons and entities acting in concert with Hospira, from commercially manufacturing, using, offering for sale, or selling Hospira's docetaxel injection product within the United States, or importing Hospira's docetaxel injection product into the United States, until the expiration of the '512 and '561 patents, in accordance with 35 U.S.C. § 271(e)(4)(B); (5) awarding plaintiffs' costs and expenses in this action; and (6) awarding plaintiffs any further and additional relief as this Court deems just and proper.

Defendant seeks a judgment and order (1) declaring that its NDA products do not and will not infringe any valid claim of the '512 and '561 patents; (2) declaring that the claims of the '512 and '561 patents are invalid; (3) declaring that the '512 and '561 patents are unenforceable; (4) declaring this an exceptional case in favor of Hospira, Inc. and awarding attorneys' fees pursuant to 35 U.S.C. § 285; (5) awarding Defendant its costs and expenses; and (6) awarding Defendant any and all such other relief as the Court determines to be just and proper.

Page 4 of 7

# 6. Amendment of Pleadings:

The parties cannot yet assess the likelihood that they will need to seek to amend the pleadings in this action, but they respectfully seek to reserve the right to file motions to amend the pleadings within the deadlines set forth in section 8.

# 7. Joinder of Parties:

The parties cannot yet assess the likelihood that they will need to seek to join parties in this action, but they respectfully seek to reserve the right to file motions to join parties within the deadlines set forth in section 8.

## 8. Discovery:

The Parties anticipate that discovery in this action will include the following topics:

- a. infringement of the '512 and '561 patents, including the composition and methods of using the accused product;
- b. the validity of the '512 and '561 patents, including the content of the prior art and secondary considerations;
- c. the prosecution history of the '512 and '561 patents.

Please see the following chart for the parties' joint proposed deadlines in the case.

| <u>Deadline</u>                        | Joint Agreed Dates |
|--|--------------------|
| Initial Disclosures                    | May 1, 2008        |
| Join Parties/Amend Pleadings           | September 26, 2008 |
| Final Joint Claim Construction Chart   | December 5, 2008   |
| Exchange of Opening Claim Construction | December 19, 2008  |
| Briefs                                 |                    |
| Fact Discovery Cutoff                  | March 27, 2009     |
| Answering Claim Construction Briefs    | January 23, 2009   |
| Markman Claim Construction Hearing     | Mid February 2008  |
| Opening Expert Reports                 | May 8, 2009        |
| Rebuttal Expert Reports                | June 12, 2009      |
| Expert Discovery Cutoff                | July 16, 2009      |
| Motions in Limine and Opening Briefs   | August 8, 2009     |
| Answering Briefs to Motions in Limine  | September 1, 2009  |
| Reply Briefs to Motions in Limine &    | September 8, 2009  |
| Pretrial Order                         |                    |
| Pretrial Conference                    | September 2009     |
| Trial                                  | October 2009       |

In addition, the parties believe that discovery in this matter will proceed in a less costly, less time-consuming, and more efficient manner if reasonable limits are placed at the outset on certain forms of discovery. In particular, the parties agree to be governed by the provisions of the Federal Rules of Civil Procedure with respect to limits on discovery (i.e., 25 interrogatories (including subparts), 10 fact depositions per side (including Rule 30(b)(6) depositions) with a deposition length of 1 day of 7 hours). For purposes of the 10 deposition limit, 7 hours of testimony pursuant to a Rule 30(b)(6) deposition notice shall be treated as a single deposition, regardless of the number of witnesses providing responsive testimony.

# 9. Estimated Trial Length:

The parties estimate that the trial will take 7-10 full court days. The parties are not contemplating bifurcation at this time. The parties will employ their best efforts to reduce the length of the trial by stipulations, use of summaries, and other expedited means of presenting evidence.

# 10. Jury trial:

Neither party has requested a jury trial.

## 11. Settlement:

Both parties are willing to consider mediation, but the parties have not jointly concluded that mediation is likely to be successful.

## 12. Other matters:

The parties agree that a protective order will be necessary due to confidential business information that will need to be exchanged in this action. The parties expect to present a stipulated protective order to the Court for its consideration.

# 13. Statement of Conference

Counsel for the parties have conferred about each of the above matters.

## **ASHBY & GEDDES**

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Dated: April 1, 2008

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